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Expert Report

J.B.D.L. Corp. d/b/a Beckett Apothecary, et al. v. Wyeth-Ayerst Laboratories, Inc., et al. (Civil Action No. C-1-01-704); McHugh Pharmacy Wynnewood, Inc. d/b/a Tepper Pharmacy, et al. v. Wyeth-Ayerst Laboratories, Inc., et al. (Civil Action No. C-1-01-745) (S.D. Ohio, Western Div. At Cincinnati)

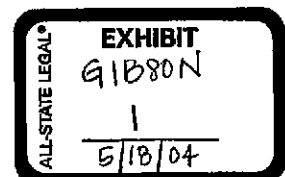


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Qualifications and Scope of Work

Qualifications

I am an expert in the field of pharmaceutical prescribing and the market forces that influence this critical process in health care. My experience spans over thirty years in diverse health care practice and business settings. My background has given me a first hand understanding of the market dynamics involved in influencing clinical decision making.

Background

My background is detailed in the attached curriculum vitae (see Attachment A). As an overview, I am a board certified internist with a subspecialty in Rheumatology. I have practiced medicine for over 30 years and have held the position of chief executive officer (CEO) at 3 different health maintenance organizations (HMOs). I have been the CEO of an 800-physician multi-specialty group practice (the UCLA Group Practice). I have been the Vice President of a major health insurance underwriter (Met-Life) with budget responsibility for over \$1.2 billion per year in health care spending. I have served as the Chief Medical Officer - insurance products - for a major hospital corporation (Sutter Health). In addition, I have chaired the Pharmacy & Therapeutics Committee at a managed care organization (Omni) and at a Pharmacy Benefit Manager (Pharmaceutical Care Network).

I served as the Medical Director for CASIO Corporation's Vertical Development Group in San Jose. This unit specialized in personal data appliances (PDAs) in a local area network (LAN) wireless environment. Specifically, our group was tasked to facilitate the generating of prescriptions by physicians on a PDA in a wireless clinical environment. Part of this assignment included the development of RxPhysician.com.

RxPhysician.com developed, with CASIO's technical assistance, a working wireless product used for prescribing which was installed in both the Santa Barbara Clinic in California and the Straub Clinic in Hawaii. The dynamics of physician decision making in pharmaceutical product selection was analyzed in depth during this engagement.

I have also worked on a retained basis with multiple software companies that have developed products for the medical environment. Some of these companies are: Software AG out of Germany; IKON Software development in Tucson AZ; STAR Information Technology Corporation, divine Software - a software development and integration company in Chicago.

My consulting practice has also involved the pharmaceutical distribution market. I have served as Longs Drug Stores chief medical consultant, strategic advisor to RxAmerica - a PBM joint owned by Longs and Albertsons, and now serve as the Medical Director for Pharmaceutical Care Network (PCN) - a Pharmacy Benefit Manager (PBM) owned by the California Pharmaceutical Association.

I currently own a privately held company, Illumination Medical, Inc. This company specializes in data mining. Illumination Medical analyzes medical and pharmacy claims to predict serious chronic illness in a population of beneficiaries before the disease

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process becomes catastrophic. The company targets interventions by case management. Illumination Medical markets its services to self funded trusts and union Taft-Hartley accounts.

I have also started a second company, the Fraud Prevention Institute (FPI) that specializes in fraud prevention within the health care industry. FPI is made up of former MediCal and FBI investigators who have been working on investigating and prosecuting fraudulent activity within health care for many years.

A listing of the publications I have authored in the preceding ten years can be found in Attachment B.

Scope of Engagement

It is my understanding that co-lead counsel – Spector, Roseman & Kodroff, P.C. and Berger & Montague, P.C. - represent a class of plaintiffs that includes most of the distribution system for pharmaceuticals within the U.S. market. This class includes the largest drug wholesalers, as well as the largest chain retailers (excluding CVS and Rite Aid who have opted out) along with the independent retail pharmacies in the U.S.

These plaintiffs assert that Wyeth-Ayerst Laboratories, Inc. ("Wyeth") had a dominant market position in oral estrogen products and unlawfully leveraged its monopoly power. The purpose and effect was to limit access of its oral estrogen competitors including its closest competitor, Cenestin, to PBM and managed care organization (MCO) formularies.

I was asked to prepare the following report in order to provide an expert perspective on how Wyeth accomplished its anticompetitive objective using exclusive dealing and market share incentive based contracts within the health care industry.

Specifically, I will analyze the cumulative effect of this successful marketing strategy and how it influenced the decision making process by American physicians as they selected estrogen products for their patients.

- My report will analyze the consequences of Cenestin being excluded, as a result of Wyeth's successfully executed marketing strategy, from substantially all major managed care formularies from Cenestin's market introduction in 1999 to the present.
- The implications of this systematic exclusion will be viewed from the clinical perspective.
- My report will focus on the technical and financial aspects involved in the delivery of pharmaceutical products in the retail pharmacy setting. I will show how Wyeth exploited these delivery structures to decrease the likelihood that Cenestin would be selected by prescribing physicians across the country.

My report is based on industry articles I have reviewed together with my own thirty years of experience in the clinical, academic, retail pharmacy and PBM industries. In preparing my report I have reviewed documents produced in the J.B.D.L. litigation provided to me by co-lead counsel.

Co-lead counsel has retained my services at a rate of \$300 per hour for research and \$500 per hour for testimony time on this project. I have testified in the past as an expert in a deposition. Specifically, I rendered an opinion in Duramed Pharmaceuticals Inc. vs.

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Wyeth-Ayerst Laboratories, Inc., Civil Action No. C-1-00-735, In the United States District Court for the Southern District of Ohio.

In preparing this report:

- I reviewed the medical literature as to the effect managed care formularies have had on the prescribing patterns of physicians.
- I consulted with my peers in practice in multiple markets across the country.
- I selectively reviewed some of Wyeth's documents that dealt with the issue of formulary structure.
- In addition, I reviewed my prior expert report and testimony in the Duramed Pharmaceuticals Inc. vs. Wyeth-Ayerst Laboratories, Inc., Civil Action No. C-1-00-735, In the United States District Court for the Southern District of Ohio.
- I drew upon over 30 years of experience in the clinical practice of medicine, Medical Group Practice Management, HMO development and management, consulting activities and PBM medical directorship.

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Summary

This paper details how Wyeth, a large and sophisticated marketing organization, used its market dominance in the conjugated estrogen therapy / hormone therapy (ET/HT) market to target and limit competition. Specifically, Wyeth identified Cenestin as a threat to its conjugated estrogen franchise and set about to attack its market entrance by addressing all levels of the prescribing and distribution chain for pharmaceutical products.

The report will explain how the pharmaceutical sector of the health care market is organized. It will trace the process by which drugs are developed and distributed throughout the system. It will explain how the decision making process by both the physician and the pharmacist have been, for the most part, curtailed and circumvented by managed care restrictions on the deliberative process.

The key for manipulating the pharmaceutical market within the managed care structure is the pharmaceutical benefit management (PBM) company. This report examines this segment of the industry in detail. Pharmaceutical products are no longer evaluated based upon their relative scientific merit within the market. Now they are favored by business decisions that are influenced by the size of the rebate paid by the pharmaceutical manufacturer to these PBMs and the managed care organizations (MCOs) that either own or hire them.

Particular attention is paid to the Formulary. How these ubiquitous lists of "preferred" drugs are created and how the co-payment structure is designed is described in detail using Wyeth's own internal documents and contracts as resource material. Formulary placement is driven by the various "rebates", "administrative fees" and "service fees" that are in almost every Reimbursement Agreement Wyeth consummated with the various PBMs and MCOs across the country.

The damaging effect these business driven decisions have in the clinical setting is told using direct quotes from physicians taken from documents generated through the discovery process within this legal action, my 30 years of experience collaborating with other practicing physicians and through my review of the published literature. Physicians are overwhelmed with the complexity of multiple disparate and non-intuitive formularies that list drugs as preferred. Physicians have learned that formularies are not intuitive. They know that a drug's preferred status is not based upon the scientific literature they read but rather on the rebate driven deals that are consummated between the pharmaceutical manufacturers and the PBMs/MCOs that make formulary decisions.

The last portion of the report examines Wyeth's marketing strategy. Early in the process of bringing Cenestin to the market, Wyeth targeted this drug as a threat to its women's health care "conjugated estrogen single source and exclusive franchise." The report, using Wyeth's own documents, traces Wyeth's leveraging of its established and dominant market position to systematically damage a competitor's entry into the market.

Wyeth created and then executed a comprehensive strategy which it titled the "Premarin Pre-emptive Plan." The plan called for both positive reinforcement of the "scientific" basis for the use of Wyeth's conjugated estrogen products to justify a preferential basis above all other options in the market; and contract based discipline for any PBM or MCO that would give access to conjugated hormone replacement/estrogen replacement (HR/ET) therapeutic options in the clinical setting.

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This report concludes by examining Wyeth's use of its market position to enforce its dominance through the contracts it negotiated and executed with most of the larger PBMs and MCOs in the market. The following is a representative, though certainly not a comprehensive, sampling of the tactics Wyeth used to advance its market objectives:

- Wyeth required that Premarin be the *exclusive, sole or preferred* conjugated estrogen on the PBM/MCO formulary.
- All products within a Wyeth "product grouping" must be *preferentially* listed on the formulary for any of the group products to be eligible for a rebate.
- Wyeth *required* that a minimum number of its product groupings must appear on formulary for the PBM/MCO to qualify for any rebates.
- Rebates were tied to Wyeth products' market share *increases*.
- Rebates were also tied to Cenestin's market share *decreases*.
- Rebate percentages *increased* as additional Wyeth products were included on formulary.
- National Drug Code (NDC) blocks were *required* to lock out competitors' products at the point of dispensing.
- Additional monies were paid as "Administration Fees" and/or "Service Fees" by Wyeth to selected PBM/MCO clients for services rendered to Wyeth.
- Specific formulary *promotional efforts* were required of some PBM/MCOs.
- Wyeth had the option of applying formulary promotional efforts to some PBM/MCO contracted physicians and pharmacies.
- PBM/MCO contracted pharmacies *must dispense as written*, without changing to a competing product.
- Wyeth leveraged their position threatening loss of rebates if competing products were put on formulary

Perhaps the most effective use of the above described contractual agreements involved the demonstration, by Wyeth's representatives, of the consequences that a PBM/MCO would face if they gave clinical access to Cenestin. The report documents instances using Wyeth's own internal documents wherein PBMs/MCOs were threatened with the loss of millions of dollars in rebate funds for providing the option of Cenestin on their formularies. These documents further substantiate that when faced with these consequences the offending PBMs/MCOs withdrew that access.

Manipulating the underwriting system that finances America's health care system has real consequences. Those consequences are magnified when a market competitor, like Wyeth, uses its dominance in the conjugated ET/HT market to inhibit competitors. Patients and their physicians are denied access to therapeutic alternatives and the market's ability to drive product cost down through cost/quality competition is circumvented.

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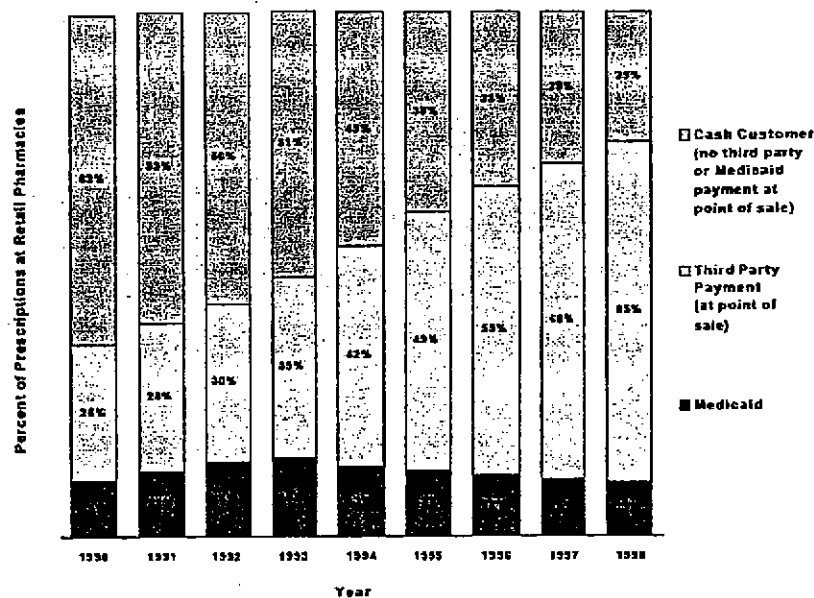
The Pharmaceutical Market in the United States

Managed care's influence on the pharmaceutical industry

The influence of managed care as the dominant third party payer within the pharmaceutical market has been profound. The number of purchasers who pay in full at the time of the transaction (referred to as cash customers) has been steadily decreasing in recent years. This category includes both those with no insurance coverage for drugs and those with indemnity coverage who file claims when the retail transaction is complete. In 1990, 63 percent of retail prescriptions involved cash customers, while 37 percent involved billing by the pharmacy to third-party payers or Medicaid. By 1998, only 25 percent of prescriptions were paid for by cash customers.¹

Copied from IMS Health Retail Method of Payment Report at 98-99.

Payment Sources for Prescription Drug Purchases, 1990-1998



Source: IMS Health Retail Method-of-Payment Report™, 1999.

It should be noted that the above trend does not represent a growth of coverage as much as it represents a shift in how drug coverage works. During the 1990s, the common approach has shifted from indemnity coverage with front loaded deductible financial liability for the patient to coverage that is managed at the point of sale with first dollar coverage.

¹ IMS Health Retail Method-of-Payment Report, 1999.

With indemnity insurance, the customer typically pays cash for the full cost of the prescription at the pharmacy and then files a claim for reimbursement from the insurer. Now most beneficiaries with private group coverage for prescription drugs have some form of managed drug benefit administered by a PBM or occasionally directly by an HMO or other underwriter. Under PBM administration, point of sale transactions are now the norm. Within such a transaction, the pharmacist uses a computer system to determine the deductible, copayment, or coinsurance, which the customer pays at the retail counter.²

Copied from
IMS Health
Retail Method
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Report at 99.

This report will describe how managed care influence on the pharmaceutical industry has resulted in evolving complex contractual relationships between pharmaceutical manufacturers, PBMs, MCOs and pharmacy providers. These contractual relationships have directly influenced physician prescribing choices, and pharmaceutical product market share. The report will also detail how Wyeth, as one of the most sophisticated competitors in this contract based market, exploited its dominant position in the ERT/HRT market to limit competition.

Wyeth is one of the health care industry's largest pharmaceutical manufacturers. It dominates a category of pharmaceuticals, known as conjugated estrogens. Wyeth's conjugated estrogen product comprises a constellation of products labeled by Wyeth as the "Premarin Family."³ The Premarin Family of products includes: Premarin (conjugated estrogens in strength per tablet ranging from 0.3 mg to 2.5 mg); Premphase (a dose pack containing a one month supply - the first half consists of 0.625 mg conjugated estrogens; the second half contains 0.625 mg conjugated estrogens and 5 mg medroxyprogesterone); Prempro (conjugated estrogens/ medroxyprogesterone acetate tablets).

The "Premarin Family" of products was tracked collectively as well as individually by Wyeth. The following, taken from a 1999 Performance Review by Wyeth illustrates this point:

"In 1998, the Premarin Family constituted 39 percent of direct brand profit to Wyeth's North American business unit equating to 19 percent of total AHP income before tax.

May 1999 net sales for the Premarin Family are \$564,046 million. This is 4% over budget and 1% over the same period last year. Projected 1999 net sales are expected to be \$1,516,037 billion, a 15 percent increase over 1998.

The Premarin Family of products continues to dominate the ERT/HRT market-place capturing 88 percent of new starts making it the most prescribed product of all categories in the United States. New prescription shares (71.9% MAT May 99) and total prescription share (73.0% MAT May 99) for the family also remains strong despite new entries into the market place (i.e. Evista and Cenestin)."⁴

² <http://aspe.hhs.gov/health/reports/drugstudy/c3.pdf>

³ WYE 180534

⁴ WYE 180534

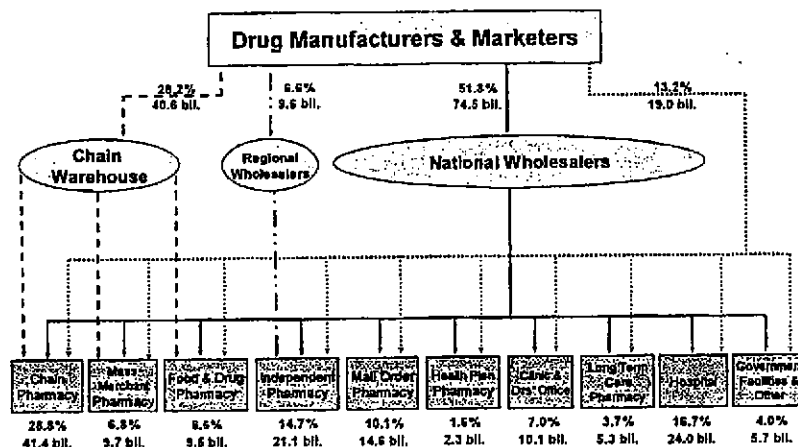
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Pharmaceutical distribution system (wholesalers, mail order and retail sales)

Prescription drug therapy costs are one of the fastest growing components within healthcare. Multiple entities are involved in the distribution of pharmaceutical products, from the manufacturer to the consumer. The primary participants in this distribution system are pharmaceutical manufacturers, wholesale distributors, retail pharmacies, mail order pharmacies, governmental agencies, physicians, and pharmaceutical benefit management companies (PBMs). The following graphic illustrates the interrelationship of each of the above entities and demonstrates the complexity of the distribution system for pharmaceuticals in the U.S. market.

Copied from Bystrom's report at 5.

Channels of Distribution for Prescription Drugs: 1999



Source: Compiled by PRIME Inc./PAI, University of Minnesota from data found in DDD Annual Class of Trade Analysis (Plymouth Meeting, PA: PAI, 1999)

Copied from presentation by Plaintiffs' expert Stephen Schondelmeyer.

Manufacturers, such as Wyeth and others, distribute their pharmaceutical products to wholesale distributors, such as AmeriSource/Bergen, McKesson and Cardinal Health and, to a lesser extent, directly to retail, chain, mail order and independent pharmacies.

Pharmacies complete the distribution process, providing pharmaceuticals to the end user, the patient, upon the written prescription from the patient's physician.

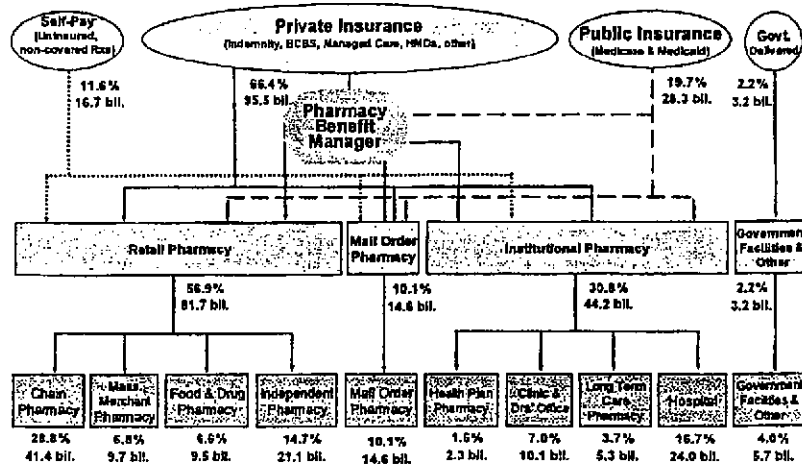
Copied from Bystrom's report at 5.

Pharmaceutical payment system

Payment cycle for pharmaceuticals

Much like the distribution process for pharmaceuticals, the payment cycle also involves multiple entities in the flow of financial remuneration from the party paying for the product back to the pharmaceutical manufacturer. The following graphic summarizes the complexity of this payment process in the U.S. pharmaceutical market.

Sources of Payment for Prescription Drugs: 1999



Copied from presentation by Plaintiffs' expert Stephen Schondelmeyer.

Pharmacy patients can be divided into two categories. The first category includes Medicare beneficiaries and those without health insurance. These "cash patients" pay for their prescriptions in total with their own cash out-of-pocket generally at retail rates.

The second category includes those individuals who are covered by a third-party health plan that includes a drug benefit. Thus, these third-party payment patients have a health plan or governmental agency paying part or all of their prescription costs.

The payment cycle for pharmaceuticals begins at the pharmacy with the patient and/or patient's health plan, paying the pharmacy their usual and customary retail price, or negotiated contract price, for their prescription.

Pharmacy Benefit Managers or PBMs function as fiscal intermediaries between a patient's health plan and their pharmacy provider, administering payment to the pharmacy on behalf of the health plan, for pharmacy services provided to their members.

The pharmacy provider pays the wholesaler or drug manufacturer if they acquired the drug directly from the manufacturer.

Copied from Bystrom's report at 5.

In some cases the drug manufacturer pays a rebate back to the PBM or MCO for specific drugs dispensed to their members that are on the PBM's or MCO's formulary. These rebates may or may not be shared with the PBM or the MCO's client, the underwriters and employers.

Copied from Bystrom's report at 6.

Establishment of acquisition cost for pharmaceuticals

Pharmaceutical manufacturers establish a suggested wholesale price (SWP) or direct catalog price (DCP) for each of their products, unique by strength, dosage strength and package size. The average of the actual acquisition prices charged by the national drug wholesalers in the market for a given pharmaceutical product is referred to as the product's "average wholesale price" or AWP.

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AWP is the industry benchmark from which most brand pharmaceutical pricing formulas among PBMs, pharmaceutical manufacturers and pharmacies are derived. AWP is published and maintained by industry sources such as the "Red Book", published by Thompson Medical Economics, and First DataBank of San Bruno, California.

Copied from
Bystrom's
report at 6.

Drug wholesalers acquire their brand pharmaceutical products from manufacturers at a discount off of the AWP price, which is then referred to as the "wholesale acquisition cost" or WAC.

Pharmacies acquire their brand pharmaceutical products from drug wholesalers at a discount off of the AWP price, usually between 17% and 21%; or directly from manufacturers at their "direct catalog price" (DCP) with possible discounts factored in.

PBMs enter into contracts with retail pharmacies with defined reimbursement terms for prescription services provided to their members. Those reimbursement terms reflect a discount off of the brand drugs' cost (e.g. 10% to 17%), plus a dispensing fee (generally \$1.00 to \$3.00 per transaction)

PBMs also enter into contracts to obtain rebates from the manufacturers in exchange for placement on the PBM's formulary. Drug manufacturer rebates are usually defined as a percentage of the DCP of the drug dispensed (e.g. 3% to 15%). The magnitude of the rebate is influenced by the in-class options available on the market (e.g. single source drugs generally have low rebate structures).

The percentage of the rebate passed through by the PBM or the MCO to the paying third-party has, historically, been highly variable. In the past, when third-party underwriters did not know about or understand rebates, the percentage was low or non-existent. As third-party understanding increased, the percentage has increased. However the opaque business practices of the PBMs and the MCOs remain problematic to the present.

Pharmaceutical manufacturers may also pay administrative fees to PBMs for administering their rebate programs. These administrative fees are usually defined as a percentage of the DCP price of the manufacturer's brand drugs being dispensed (e.g. usually 1% to 3%). PBMs may or may not pass on some of the manufacturer's rebate received to their client, but generally do not pass on the administrative fee received from the manufacturers.

At the point-of-service in a retail pharmacy when a patient receives their prescription they pay 100% of their prescription cost if they are a "cash" patient or, if they are a third party patient, they pay a portion of their prescription cost, the copayment, with the remainder of the cost billed to their health plan that subsequently pays the pharmacy.

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Managed care's dominance of the pharmaceutical market in the United States⁵

Background

Managed care now dominates health care in the United States. By 1999, only 8 percent of persons with employer-sponsored health insurance coverage had traditional indemnity insurance. This reflects a sea change in the past two decades -- not just in the financing of health insurance but also in the way medicine is practiced.

The rapid growth of managed care is not primarily due to enthusiasm for this approach on the part of patients or providers. Patients have had mixed reactions to managed care; they like the low copayments and reduced paperwork that accompanies the filing of claims but view some managed-care practices as emphasizing cost control over quality. In fact, there is widespread concern among the public, physicians, and legislators about the effect of managed care on the quality of care.

Purchasers have rarely chosen health plans on the basis of the quality of care. Assuming that licensure of plans and licensure of providers are sufficient to ensure high quality, they have chosen plans primarily on the basis of price.

Copied from
New England
Journal of
Medicine.

The leading MCOs

The following organizations have significant HMO enrollment or either own or are Blue Cross Blue Shield organizations that are trying to build regional positions and have large Preferred Provider Organization (PPO) enrollment.

	*Total HMO Lives	HMO Lives as Percentage of Insured Lives	
		2002	2001
Kaiser	8,330,000	100%	100%
Aetna	8,131,000	59%	65%
CIGNA	6,750,000	52%	49%
United	6,325,000	36%	64%
Humana	5,453,900	82%	82%
WellPoint	4,973,000	38%	40%
Anthem	4,941,000	45%	45%
Health Net	4,855,000	89%	89%
PacificCare	3,012,500	96%	99%
Coventry	1,640,000	81%	86%
Oxford	1,549,600	97%	100%

Copied from
Managed
Markets
Diagnostic
Report.

⁵ The New England Journal of Medicine; R. Adams Dudley, M42.D., M.B.A., Harold S. Luft, Ph.D.; University of California, Health Net San Francisco; April 5, 2001; Vol. 344, No. 14

Highmark	1,340,900	42%	41%
Mid Atlantic Medical Services, Inc. (MAMSI)	758,900	38%	NA%
Harvard	718,900	96%	96%
Blue Care Network	676,300	100%	100%

* Note: HMO enrollment includes Commercial, Medicare and Medicaid lives.

Data Source: HSG & AHP 295619 (Managed Markets Diagnostic Report – Tactical; September 2003).

HMO enrollment declined 4% overall in 2002. A shift of lives to PPO products is the primary factor in overall HMO enrollment decline.⁶

Copied from
Managed
Markets
Diagnostic
Report.

Effects of Managed Care

Effect on Physicians

Nearly 91 percent of physicians contracted with MCOs in 2001. For those who do, almost 46 percent of practice revenue is derived from managed care sources, up 3 percentage points from 1997. In addition, the average number of managed care contracts per physician rose during this period – from 12.4 to 13.1 – despite consolidation in the managed care industry.⁷ As a result, physicians are acutely aware of managed care restrictions placed upon them, such as drug formulary restricted prescribing behavior.

Copied from
Managed Care Magazine.

Effect on Patients

Managed care has resulted in major changes for patients and their experience with health care. Measures adopted by managed-care organizations to control costs or improve the quality of care, or both, include primary care gatekeeping, preauthorization of referrals, utilization review, profiling of physicians (monitoring of their patterns of utilization or the quality of their care), pharmaceutical restrictions, practice guidelines, case management, and most recently, disease management. Patients' reactions to these measures depend primarily on whether they are perceived as attempts to limit expenditures or to ensure proper care. Thus, gatekeeping is often not well received, because people rarely believe its purpose is to maintain or improve the quality of care.^{8,9}

Gatekeeping intertwines the roles of physicians and healthcare organizations. This enmeshment benefits delivery systems because the population trusts healthcare organizations much less than it trusts doctors.¹⁰

Copied from Health
Services Research &
Development Center.

Effect on Employers

The employers' desperation resulting from unrelenting increases in the cost for the pharmacy benefit is now demonstrating itself in the market. As companies put the finishing touches on 2004 employee benefit design changes, they stepped up adoption

Copied from
Managed Care Weekly.

⁶ AHP 295619 (Managed Markets Diagnostic Report – Tactical; September 2003).

⁷ <http://www.managedcaremag.com/archives/0301/0301.compmo.html>

⁸ A verdict on gatekeepers [editorial]. *New York Times* 2001 Nov 15:30

⁹ Mechanic, D. & Schlesinger, M. The impact of managed care on patients' trust in medical care and their physicians. *JAMA* 1996; 275: 1693–1697.

¹⁰ Health Services Research and Development Center, Department of Health Policy and Management, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD 21205, USA; <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=152368>

of time-tested approaches to slow spending on prescription drugs - and are evaluating a few new strategies.

Techniques like mandatory mail-order fulfillment requirements and four-tier pharmacy designs have been around for a few years but used by a minority of payers. Continued increases in health premiums have led more employers to embrace those techniques to lower drug spending.¹¹

The most common plan design change for 2004 is to require enrollees to use mail-order services rather than retail pharmacies to fill prescriptions for chronic-illness medications. For years, employers have encouraged members to use mail-order services for maintenance medications, since such services can be less expensive, but have not made their use mandatory.¹²

Employers are now generally more aggressive than are health insurers in pushing members to convert prescriptions from retail to mail-order fulfillment. Employers are continuing to widen the difference between co-pays for second- and third-tier formulary medications. They are also stepping up the number of drugs subject to step-therapy requirements, in which a patient must first try a generic or lower-cost drug before a brand-name or higher-cost medication would be covered.^{13,14}

Copied from
Managed Care
Weekly.

Pharmacy Benefit Managers (PBMs)

The PBM's role in the distribution process

In response to dramatic managed care growth and the resulting unmet need for pharmacy benefit management, specialized companies came into existence to provide prescription drug benefit management for a broad spectrum of customers. These pharmacy benefit management companies, commonly referred to as PBMs, have taken a dominant role in the management of prescription drug benefits.

PBMs originally developed from insurance claim processing and mail order prescription companies into the management of drug benefits. PBMs manage pharmacy benefits for employers, insurance companies, managed care groups, and Medicaid. There are approximately 100 PBMs in the U.S., but the top four companies dominate the industry.

PBMs may provide administrative services and/or clinical services to their clients. Administrative services include client service, pharmacy network administration, mail pharmacy, claims adjudication, member services, and manufacturer contracting and rebate administration. Clinical services range from formulary management to sophisticated disease management programs.

In general, self-insured employers and insurance carriers outsource both administrative and clinical services to a PBM. Managed Care Organizations (MCOs), including HMOs, PPOs and some insurers and self funded trusts may elect to retain formulary and clinical control, including manufacturer contracting, and outsource only administrative services, such as claims processing and benefit administration, to a PBM.

Copied from
Bystrom's
report at 8.

¹¹ "Managing Drug Costs"; *MANAGED CARE WEEK*; Nov 11, 2003,

¹² "Managing Drug Costs"; *MANAGED CARE WEEK*; Nov 11, 2003,

¹³ "Managing Drug Costs"; *MANAGED CARE WEEK*; Nov 11, 2003,

¹⁴ <http://www.aishealth.com/DrugCosts/MCWAgressive.html>

PBM services revolve around the drug benefit designed by the client. The benefit design determines the therapeutic categories of drugs that are covered -including whether cosmetic, lifestyle, and over-the-counter (OTC) drugs are reimbursed-and the extent to which generics and formulary drugs are mandated.

Copied from
Bystrom's report
at 8.

PBMs function as aggregators in the pharmacy industry. They aggregate large patient populations through their contracts with health plans, self-insured employers, municipalities, and other clients. These large groups of prescription purchasers provide leverage for the PBMs in their negotiations with pharmacies when contracting for their prescription reimbursement rates.

PBMs also aggregate pharmacy providers to create pharmacy networks for their clients to which their members are directed when needing prescription services. PBMs often leverage participation in their pharmacy network, or potential exclusion from their network, in their prescription reimbursement negotiations with pharmacies for discounted prescription pricing.

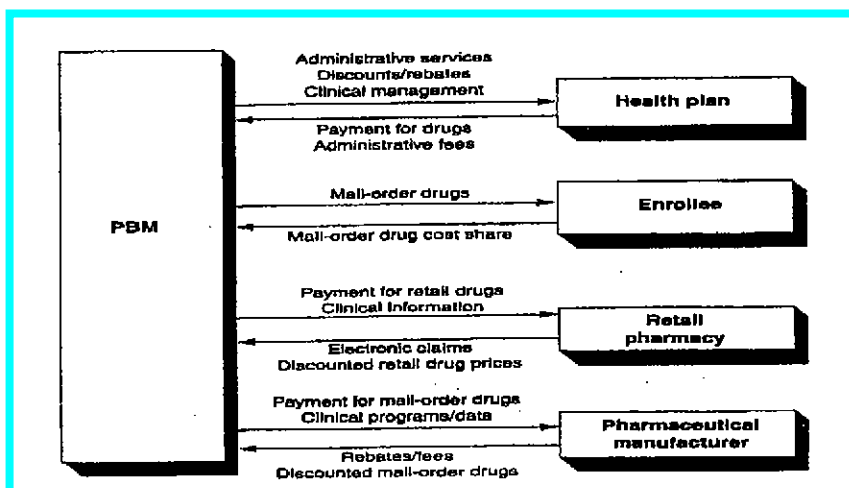
PBMs also rely on their large aggregated population groups for leverage when negotiating with drug manufacturers for rebates for their managed care organization (MCO) clients. These large population groups give the PBMs the ability to influence market share of pharmaceutical products through their formulary process and pharmacy benefit plan design features. Market share is a very important issue to pharmaceutical manufacturers. The rebates pharmaceutical manufacturers pay to PBMs are often tied to the market share performance of their pharmaceutical products or the structural incentives the PBMs build into their formularies to favor the manufacturer's products. The amount of the rebate returned to the client health plan is difficult to quantitate on an industry level given the opacity of business practices endemic within the industry (see below).

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at 9.

PBM overview

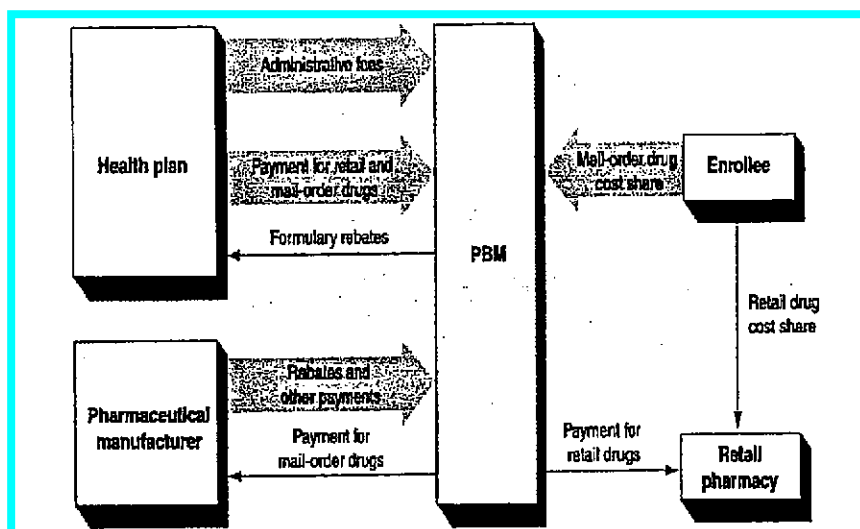
The role of the PBM within the pharmaceutical market is summarized in the following graphic.¹⁵ The graph demonstrates the market relationships between the PBM and the structural components that make up the market.

¹⁵ Federal Employees Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies (January 2003); www.gao.gov



Copied from GAO presentation "The Role of PBMs in the Federal Employees' Health Benefits Program" at 8.

The PBM's sources for compensation are summarized as follows:



Copied from GAO presentation "The Role of PBMs in the Federal Employees' Health Benefits Program" at 26.

PBM services / client contracts

PBMs market themselves as having the ability to manage pharmacy benefit costs for their clients in several ways, two of which are (1) obtaining retail pharmacy price discounts, and (2) obtaining rebates from brand pharmaceutical manufacturers.

Adapted from Bystrom's report at 10.

PBMs develop national pharmacy networks that are under contract to provide prescription dispensing services at negotiated reimbursement rates, offering discounted prices to their client's members. PBMs will often negotiate price discounts with retail pharmacies reflective of the size of the population base represented by their clients' members and the number of competing pharmacies included in the PBM's pharmacy network; the larger the population of members and the more restrictive the pharmacy

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network, the greater the discount negotiated by the PBM for pharmacy services on behalf of their client.

PBMs offer formulary services to their clients as an intended cost containment tool. Formularies were originally intended to assist physicians in making cost-effective drug therapy choices. Formularies also attract rebates from the brand pharmaceutical manufacturers which have their products listed on the PBM's formulary.¹⁶

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Bystrom's report
at 10.

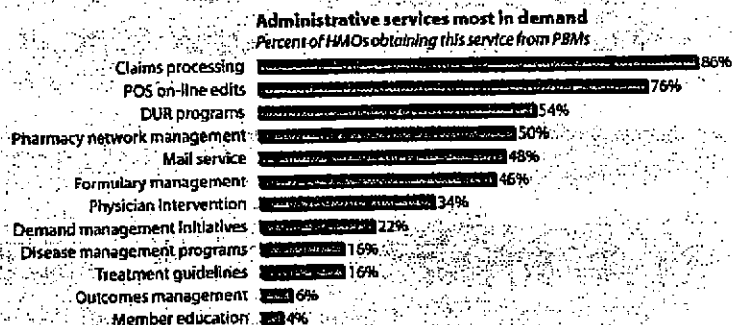
The following graph demonstrates the scope of services delivered by most of the larger PBMs and the relative market value each holds.¹⁷

What PBM services are in demand

According to a recent industry survey, the PBM services used most frequently by large HMOs involve administering the pharmacy benefit, claims processing, network management, and formulary development. These are the low-hanging fruit of cost-containment programs.

The more complex process of advancing utilization management involves the last six categories in this table, and with the last four — from disease management to member education — the focus is on the demand side of the equation and appropriate utilization of prescription drugs. These are more difficult programs to implement from a centralized locus operandi, especially when the member is the focus of the initiative.

As payers become more aware of opportunities to improve the quality of care for their subscribers, demand management, in conjunction with disease management initiatives, will become more important.



SOURCE: MANAGED CARE PHARMACY PRACTICE, R. P. HANAWALT, ED., GAITHERSBURG, MD: ASPEN PUBLISHERS

POS — point-of-service
DUR — drug utilization review

Copied from
Managed Care
Magazine.

PBM Effectiveness in controlling cost

PBMs manage about 70% of the more than 3 billion prescriptions dispensed in the U.S. annually. There is, however, considerable skepticism as to the effectiveness of PBMs in controlling overall pharmaceutical cost trends. Empiric evidence is lacking as to the effectiveness of PBM cost control techniques. Prescription expenditures continue to increase and have been the most rapidly growing component of the health care cost equation in recent years. This indicates that cost control mechanisms have not been effective.

Furthermore, misaligned PBM priorities appear to be actively driving pharmacy costs upward. Payers, such as MCOs and employer groups, are now seeking solutions to

¹⁶ "Concepts in Managed Care Pharmacy Series: Formulary Management," The Academy of Managed Care Pharmacy, April 30, 1998. www.amcp.org. Link to Concepts in Managed Care Pharmacy.

¹⁷ MANAGED CARE, Tim Sawyers, March 2000.
<http://www.managedcaremag.com/archives/0003/0003.pbmeval.html>

contain drug costs and eliminate conflicting priorities. Leading solutions include in-house control of pharmacy benefit functions and best value drug utilization.

PBMs generate revenue streams from misaligned formulary design, inappropriate drug switching, buy and bill practices, non-adherence to maximum allowable cost (MAC), markup of contracted services, and/or repackaging & re-pricing tactics. This is particularly evident when the PBM controls the retail network and mail order delivery system. Innovative payers are questioning the PBM practice of moving rebates to unaccounted revenue line items such as data management fees that shelter the PBM from sharing manufacturer incentives.

Escalating litigation in 2003, against traditional PBM financial practices and their unwillingness to accept fiduciary responsibility, has prompted clients and insurers to seek alternatives in managing their prescription drug benefits. Pharmacy payers are now seeking self management solutions to formulary design, rebate administration, network management and other pharmacy benefit services.

The following graph gives an overview of the services provided by PBMs as of 1999.¹⁸

Services	Commercial/ Group	Medicaid	Medicare
Claims Processing	94.2%	93.6%	94.4%
POS Edits and Mentoring	89.9%	90.3%	86.1%
DUE/DUR	79.7%	77.4%	72.2%
Pharmaceutical Manufacturers' Contract Management	79.7%	74.2%	80.6%
Generic Substitution	76.8%	89.9%	69.4%

Source: Novartis Pharmacy Benefit Report

Emron IMS HEALTH

Copied from
Novartis Pharmacy
Benefit Report.

Acronym definitions:

POS – point-of-service

DUE –drug utilization evaluation (another term for DUR)

DUR – drug utilization review

As to how effective all of the above PBM services are in actually controlling the cost trends for the pharmacy benefit is open to debate today. It is generally accepted within the industry that exposing the patient to the cost of pharmaceutical products and encouraging the use of generics product are very effective in reducing the inflationary trend for the benefit. The rest of the above services including rebates, POS edits, formularies, disease management programs, mail order drugs and DUE/DUR activities are coming under increasing skepticism as to their effectiveness.

¹⁸ Novartis Pharmacy Benefit Report 2000.

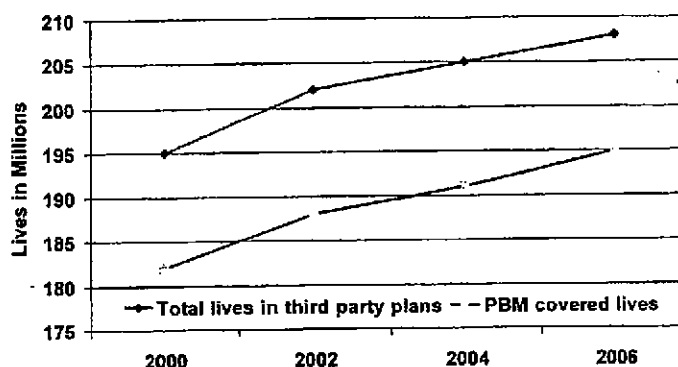
PBM market

The total number of lives enrolled in benefit programs managed by PBMs has grown slowly over the last four years from 181 million in 1998 to 187 million in 2003. However, PBMs administer prescription benefits for nearly 94% of those with a pharmacy benefit program and this growth closely tracks the increase in total lives enrolled in third party plans.¹⁹

The following demonstrates the prior and projected growth for the PBM industry.

Copied from
Managed
Markets
Diagnostic
Report.

PBM Covered Lives Market Potential



SOURCE: HSG & *Managed Markets Diagnostic Report; September 2003; AHP 295633

PBM business model

Many PBMs that once earned most of their revenue by administering the pharmacy benefit for payers now earn a large portion of their income from drug companies that pay them undisclosed rebates and other financial incentives for promoting certain pharmaceutical products. The move to this business model has been driven by the fact that the PBMs' clients demand competitive bids that dictate no administrative fees for claims processing; no fees for pharmacy network management; no fees for data analysis and client support; and, in some cases, no mail service dispensing fees.²⁰

PBM failure to perform as a fiduciary for the client

In a business model where PBMs have long received the majority of their revenue from a source other than their clients - specifically from drug manufacturers delivering rebate revenue for formulary product placement- it is not surprising that purchasers of PBM

Copied from
HealthLeaders
News.

¹⁹ *Managed Markets Diagnostic Report; September 2003; AHP 295618 – AHP 295653

²⁰ Federal Employees Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies (January 2003); www.gao.gov

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Copied from
HealthLeaders
News.

services are becoming restive with this conflict of interest and, in many cases, seek financial restitution.

Critics charge, not altogether unfairly, that the current rebate structure creates a built-in conflict of interest for PBMs because it may inappropriately put the interests of PBMs and pharmaceutical manufacturers before those of the customer health plan, employer or member.²¹

As a direct result of the above, many payers of health care services are currently arriving at a consensus – the PBM service product that now controls pharmacy transactions for 200 million Americans, as currently configured, has outlived its usefulness. The perception is widely held that many of these vendors have been so co-opted by the pharma manufacturers that they no longer serve the best interests of the customer.

Health plan sponsors are now asking PBMs to fully disclose all rebates and revenue sources to demonstrate their commitment to a relationship based on incentive alignment. Disclosure itself should neither increase nor decrease the cost of prescription drugs to consumers, but it will foster an appropriate platform for payors to make informed decisions about their clinical and financial (pricing) strategies.

These payors are now looking for PBMs that will provide quality pharmaceutical care management to members while managing the pharmacy benefit costs for customers. Specifically, they want to see PBMs with a business model wherein they are compensated for the clinical and administrative expertise required in the delivery of and the efficiency with which these services are delivered.

The above is only possible through a transparent revenue model that provides financial incentives for PBMs to always encourage utilization of the most clinically appropriate drug at the lowest possible cost, which was the original charter for the PBMs. The most effective method to manage costs is to drive utilization to the most cost-effective product rather than toward products because of their higher rebates.²²

PBMs such as AdvancePCS, of Irving, Texas, and the other three major ones -- Medco Health Solutions Inc., Express Scripts and Caremark -- have been dogged in recent years by litigation and investigations that question whether the companies save much money for their clients.

It is now widely perceived in the market that the large PBMs are steering patients to more-costly medications to maximize their returns on performance based rebate contracts with pharma manufacturers. This inherent conflict of interest behavior is compounded by the PBMs not passing on the rebates they get from drug makers as a result of this activity. As a result, numerous legal actions have been brought against the major PBMs on the basis of these business practices.

In short, full service PBMs have damaged their reputations in the market with the lack of transparency they have consistently demonstrated in their business practices.

²¹ PBMs: Change Business Model or Fight Losing Battle"; Tim Dickman; for *HealthLeaders News*, Oct. 31, 2003
(http://www.healthleaders.com/news/feature1.php?contentid=49601&CE_Session=a4a6ad36ea527022a26c43f93ea14c27)

²² PBMs: Change Business Model or Fight Losing Battle"; Tim Dickman; for *HealthLeaders News*, Oct. 31, 2003
(http://www.healthleaders.com/news/feature1.php?contentid=49601&CE_Session=a4a6ad36ea527022a26c43f93ea14c27)

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PBM consolidation

Industry growth and consolidation have resulted in a few PBMs controlling the industry.²³ Wyeth documents take note of the fact that "consolidation has recently taken the number of PBMs from 80 to 55, with three firms (AdvancePCS, Merck-Medco, and Express Scripts) dominating the market. Today (2001), the top five PBMs control more than 90% of the covered lives in the segment, which is an increase from only 65% five years ago. Currently PBMs provide services to over 114 million lives."²⁴

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WYE167222 -
WYE167223.

In addition, some larger PBMs rent their formularies to smaller PBMs, passing back the rebates that are paid by manufacturers for brand drugs purchased by the smaller PBM's clients' members. This practice of renting out formularies aggregates additional population groups for the larger PBMs to use in their negotiations for rebates from the pharmaceutical manufacturers.

Copied from
Bystrom's report
at 9.

The PBM market can be segmented in various ways.

"The most common way to segment PBMs is by their size. Size is measured either by lives, claims processed, or revenues. Using this method, there are basically three categories of PBMs. The three large PBMs have over 45 million lives each. They have the highest number of claims processed, dollar value of prescription processed and revenues. These PBMs are the most sophisticated and offer the broadest range of services to their clients including mail service pharmacy.

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WYE167223 -
WYE167224.

There are approximately 15 PBMs in the middle tier. These PBMs range between 7 and 20 million lives each. There is some variation in this group with the scope of their service capabilities and their clients. Some PBMs in the middle tier have a strong geographic foothold while others are more national in scope but not as large as the top three.

The remaining PBMs tend to be much smaller in size and more limited in their service capabilities. There are several niche PBMs in this group as well. Some are strictly claims processors. Others may only service a particular client type such as local governments or small employers."²⁵

PBM Market Segments

Segment	Description	PBM	Covered Lives
Tier 1	>20 million covered lives.	AdvancePCS	85,000,000
		Merck-Medco	65,000,000
		Express Scripts	48,000,000
		Caremark Rx	20,000,000

Copied from
Bystrom's report at
9-10.

²³ WYE167220-167231; Pharmacy Benefit Management Companies Business Plan; Kimberly France, Marketing Manager, Healthcare Systems Marketing; June 19, 2001.

²⁴ WYE 167223

²⁵ WYE 167223-167224

Segment	Description	PBM	Covered Lives
Tier 2 & Retail	Smaller PBMs and those owned by retail chains	New Eckerd Health Services	5,000,000
		Prescription Solutions	5,000,000
		Restat	7,000,000
		Walgreens Health Initiatives	4,000,000
Captives	Insurer-owned PBMs	Wellpoint	28,000,000
		Aetna	5,000,000
Other	Other PBMs		128,000,000
		Total	400,000,000

Source: HCFA Study of the Pharmaceutical Benefit Management Industry; HCFA Contract No. 500-97-0399/0097; Dr. Peri Iz; June 2001

Copied from Bystrom's report at 9-10.

While 50 companies are classified as PBMs, there are four significant industry leaders with three PBMs claiming more than 75% of the estimated 188 million lives covered by the PBM industry.

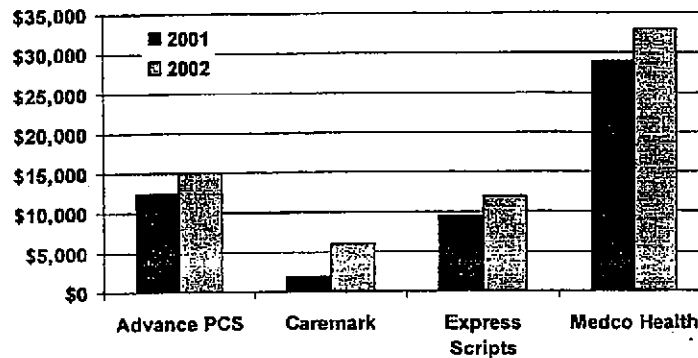
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The PBM revenue for the leading companies is demonstrated below (I did not include the MedImpact data displayed in the referenced document in that it did not fall into this criteria).²⁶

²⁶ "Managed Markets Diagnostic Report; September 2003; AHP 295618 – AHP 295653.

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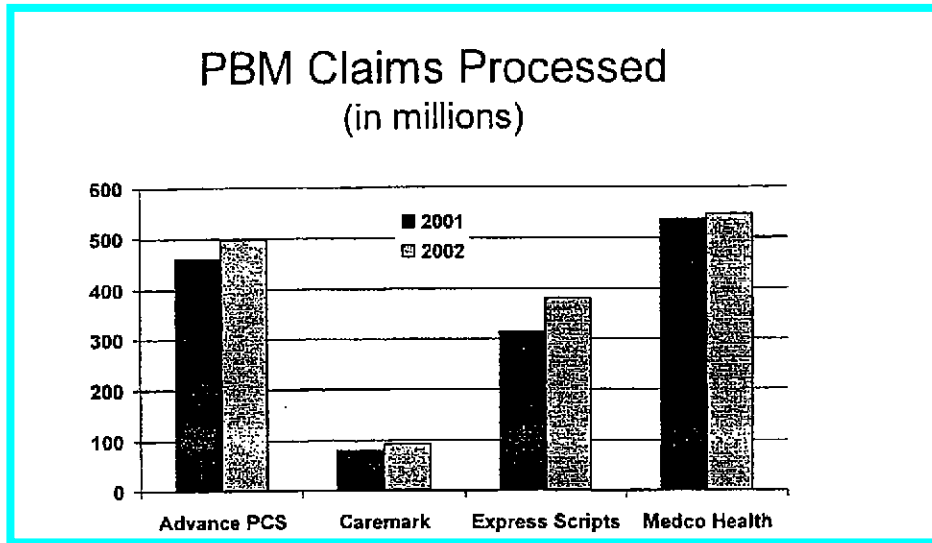
PBM Revenue (in \$ millions)



SOURCE: HSG & *Managed Markets Diagnostic Report; September 2003; AHP 295634

While enrollment numbers can be inflated or double-counted, the number of claims processed is much more difficult to manipulate and can be used to verify PBM size. The claims processed by the top five PBMs in 2002 was over 1.61 billion compared to 1.5 billion in 2001, representing a 7% increase. The industry is likely to witness additional consolidation in order to stay competitive and achieve economies of scale. The number of claims processed by the leading PBMs is demonstrated below (once again I omitted the MedImpact data):²⁷

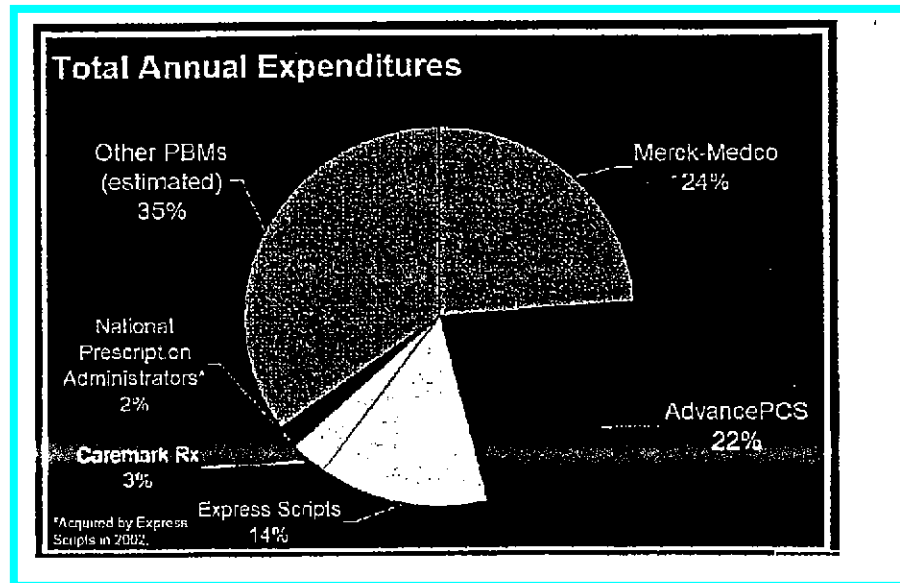
²⁷ AHP 295635.



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AHP295635.

SOURCE: HSG & *Managed Markets Diagnostic Report; September 2003; AHP 295635

The following graphs demonstrate the PBM market share in 2002 by total annual expenditures, prescriptions per year & total covered lives.²⁸

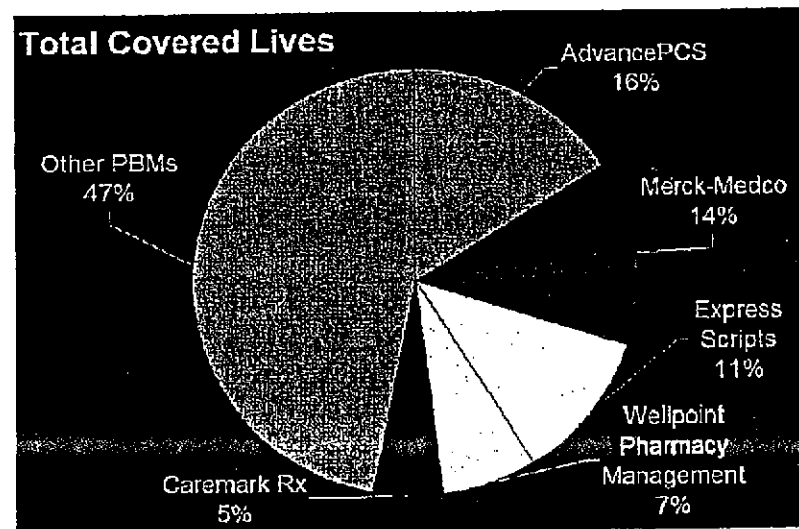
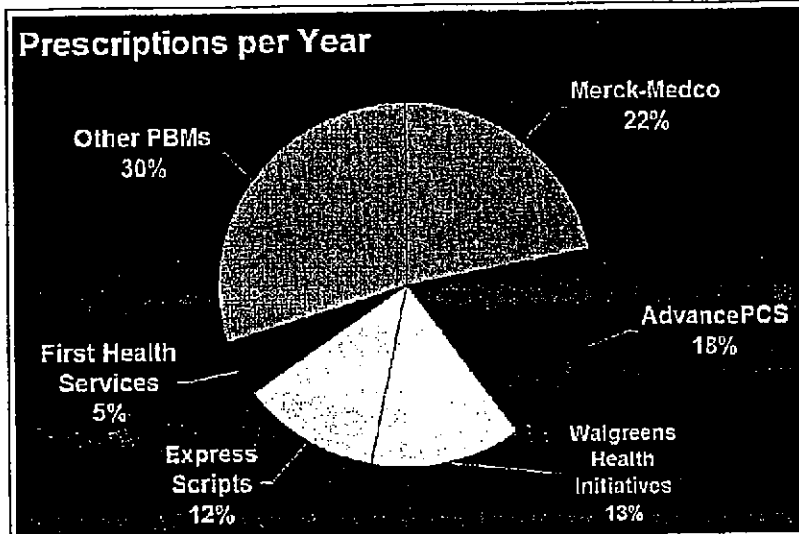


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to Managed Care
Strategies at 9.

²⁸ AIS, A Guide to Drug Cost Management Strategies. www.ftc.gov/ogc/healthcarehearings/docs/030626richardson.pdf

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Managed Care Strategies
at 10-11.



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PBM Market Segments

PBM Industry Participants by Covered Lives		
<u>Over 20 million</u>	<u>10-20 million</u>	<u>Less than 10 million</u>
<ul style="list-style-type: none"> • AdvancePCS • Caremark Rx • Express Scripts • Merck-Medco • WellPoint Pharmacy Management • MedImpact Healthcare Systems 	<ul style="list-style-type: none"> • Eckerd Health Services • Aetna US Healthcare • First Health • Pharmacy Services Group • PharmaCare 	<ul style="list-style-type: none"> • Anthem Prescription Management • Inteq Group • MIM Corp. • National Medical Health Card Systems • Prescription Solutions • RESTAT • RxAmerica
Source: Morgan Keegan & Company, <i>PBM Industry Overview</i> , June 25, 2002.		

Copied from Health Strategies Consultancy presentation, "PBMs: The Basics and an Industry Overview" at 12.

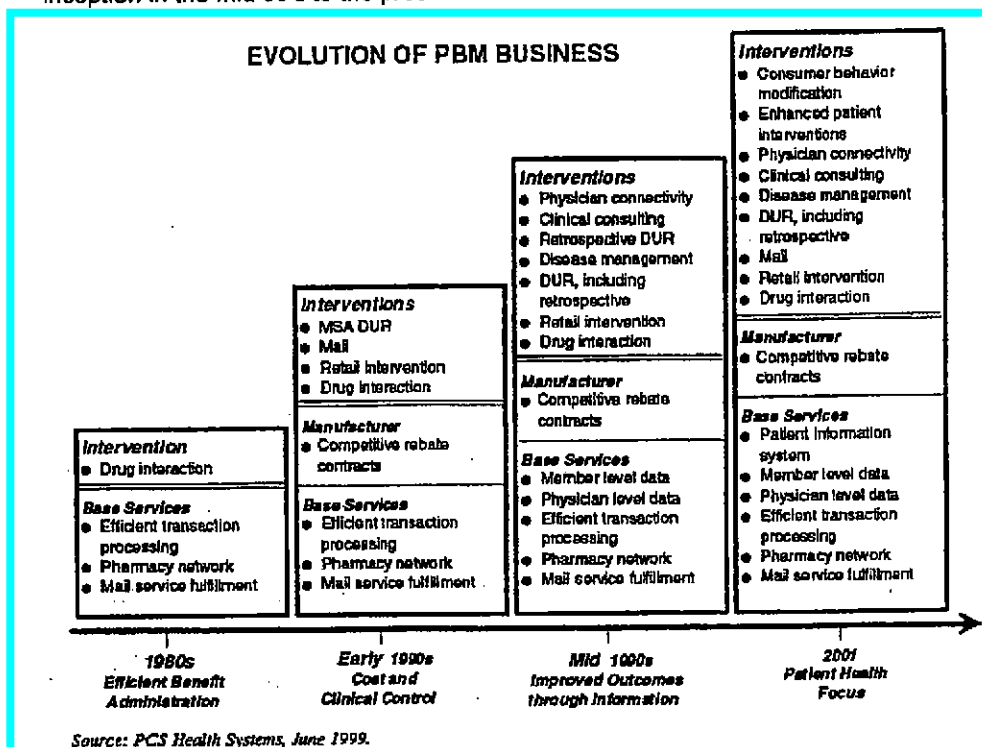
The six largest PBMs each manage greater than 20 million covered lives, own mail pharmacies, and have extensive retail pharmacy networks with national coverage.

Copied from Bystrom's report at 10.

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The evolving role of the PBM in the market

The following summarizes the role of the PBM in the managed care market from their inception in the mid 80's to the present.



Copied from National Health Policy Forum Issue Brief No. 749, "The ABCs of PBMs" at 3.

Drug Formularies

Formulary management is the process of developing and maintaining a list of "preferred" drugs, with the intent of promoting cost-effective clinical care. When multiple drugs exist with similar clinical results, issues such as cost-effectiveness and maximizing manufacturer rebates determine which drugs are included on the formulary. A drug's inclusion on formulary is a prerequisite for that drug to be eligible for rebates from its manufacturer. In addition, some rebates are structured such that product positioning as preferred, favored or even exclusive on the formulary is a requirement. Other contracts add performance benchmarking to the rebate payment structure.

All of the above can be summarized as follows: If a PBM can move market share, then the rebate formula is enhanced based upon the product's realized market performance. Formularies are created and administered by PBMs and MCOs today within these contractual realities.

A formulary is a continually updated list of brand and generic drugs developed by the Pharmacy and Therapeutics (P&T) committee of the PBM or MCO. The committee generally meets on a quarterly schedule and reviews drugs that have cleared FDA approval and are now on the market.

Copied from Bystrom's report at 10.

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